



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO. 09/294,643	FILING DATE 04/19/99	FIRST NAMED INVENTOR GRANADOS	ATTORNEY DOCKET NO. R BTI-39-CIP
-------------------------------	-------------------------	----------------------------------	-------------------------------------

020808
BROWN PINNISI & MICHAELS
400 M & T BANK BUILDING
118 NORTH TIOGA ST
ITHACA NY 14850

HM22/0901

EXAMINER IBRAHIM, M

ART UNIT 1649	PAPER NUMBER 4
------------------	-------------------

DATE MAILED: 09/01/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/294,663

Applicant(s)

Granados et al

Examiner

Medina A. Ibrahim

Group Art Unit

1649



☒ Responsive to communication(s) filed on Apr 19, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-19 is/are pending in the application.

Of the above, claim(s) 2, 8, and 11-19 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 3-7, 9, and 10 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-19 are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1649

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1,3-7, 9-10, are drawn to gene encoding protein and transformed host cells , classified in class 536, subclass 23.5, for example .
 - II. Claim 11, is drawn to fusion protein , classified in class 435 , subclass 69.7 .
 - III. Claim 12, is drawn to isolated IIM protein , classified in class 530 , subclass 858 .
 - IV. Claims 13-14 , and 19, is drawn to gene encoding antibody to IIM protein and transformed hosts , classified in class ⁹⁰⁰ , subclass ³⁰² .
 - V. Claims 15-17, are drawn to antibody to IIM protein , classified in class 530 , subclass 387.1.
 - VI. Claim 18, is drawn to DNA encoding fusion protein , classified in class 536 , subclass 23.4 .
2. The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III, IV, V, and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or ~~different~~ different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, have different modes of operation .

Art Unit: 1649

Gene encoding IIM protein and transformed hosts of Group I are not required by either Groups II, III, IV, V, or VI. Each invention differs both in structure, physiology and function which as result contributes different effects.

3. Because they have acquired a separate status in the art as shown by their different classification, subject matter and fields of search, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed inventions I, and IV.

A species election is required from one of the following:

- A. Transformed virus, claim 1.
- B. Transformed microbe, claims 1-2, 8, 13-14, 19
- C. Transformed plant, claims 1,3-7, 9-10
- D. Transformed animal, claims 1, 13-14, and 19

The species differ with respect to their structure, physiology and function, a person of ordinary skill in the art would not envision one in view of the other. Therefore, they are patentably distinct species in view of each other.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon,

Art Unit: 1649

including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. During a telephone conversation with Christopher Michaels on Aug. 19 a provisional election was made with traverse to prosecute the invention of group I, claims 1, 3-7, and 9-10 with the plant species. Affirmation of this election must be made by applicant in replying to this Office action. Claims 2, 8, 11-19, and species A(virus), B(microorganism), D(animal) are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

Art Unit: 1649

amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Specification

6. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the phrase ---(glutathione-S-transferase)--- should be inserted after the word "transfer molecule" in page 4, line 20.

ERRORS

In the specification, page 4, line 2, "commoon" may be changed to ---common---; line 20, between the words "molecule" and "said"---, wherein---may be inserted.

Page 11, line 11, "threonine-" may be changed to---threonine---.

Page 21, line 12, "Tn" may be changed to---TnGV---.

Page 25, line 6, between the words "OBs" and "from"----(Occlusion Bodies)---may be inserted.

Page 31, line 1, "viurs" may be changed to---virus---.

Page 33, line 32, "exits" may be changed to---exist---.

Page 34, line 11, the word "I'M" may be changed to---PM---; line 15, "immunocytochernical" may be changed to---immunocytochemical---.

Page 36, line 27, "can1" may be changed to---can---.

Page 39, line 22, "tranfer" may be changed to---transfer---.

Page 40, line 14, "injectec" may be changed to---injected---.

Art Unit: 1649

Claim Objections

Claim 1 is objected to because of the following informalities: the use of the abbreviation IIM without clarification. changing "IIM" to--- IIM (Invertebrate Intestinal Mucin) would be an appropriate correction.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,3- 5 and 9-10 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in its recitation of the phrase " a host " which is not clear wether this host refers to these cited in the claim. Replacement with the phrase--- the plant--- would obviate this rejection. The claim is also indefinite in its recitation of the phrase"a functional form"which is not further defined in the claim. It is not clear what is the Applicant's intended function for the IIM protein.

Claims 3 is indefinite in their recitation of " A recombinant DNA" with out further limiting in its composition or its SEQ ID NO. Recombination occurs in nature, and the phrase does not clearly distinguish the claimed DNA.

Art Unit: 1649

Claim 4-5 recites the limitation "A recombinant DNA" in claim 3. There is insufficient antecedent basis for this limitation in the claim. An appropriate correction could be replacement of---The recombinant DNA---.

Claim 9 recites the limitation "transfer molecule" in claim 6. There is insufficient antecedent basis for this limitation in the claim.

Claim 10 recites the limitation "An expression vector" in claim 7. There is lack of antecedent basis for this limitation. Replacement of---The expression vector would obviate this rejection.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 U.S.C. 101 because it is directed to non-statutory subject matter. A virus, microorganism, plant, or animal are product of nature and can not be claimed. Replacement of --- A transformed virus, microorganism, plant, or animal would overcome the rejection---

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1649

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1, 3,6-7, and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kramer et al (U.S Patent # 5,866,788) over Wang et al (The Journal of Biological chemistry, Vol. 272:26, pp. 16663-16669).

Claims are drawn to a plant transformed with a gene expression vector comprising a promoter sequence fused with a nucleic acid sequence from *Trichoplusia ni* larva encoding IIM (Invertebrate Intestinal Mucin) protein expressed in a host or a plant, wherein the transformed plant exhibit resistance against insects damages. Claims are also drawn to method of producing and recovering IIM protein in insect cells (Hi-5) using baculovirus expression vector.

Kramer et al teach plant transformed with a plasmid expression vector comprising a insect chitinase gene from tobacco hornworm (*M. sexta*) encoding chitinase protein under the control of a promoter, for insect damage control, and shown that recombinant insect chitinase have insecticidal activities against tobacco hornworms (see, e.g., paragraph bridging columns 17 and

Art Unit: 1649

18). Kramer also teach method of producing and recovering M.sexta protein from cell (Trichoplusia ni Hi-5) lysates.

Kramer et al do not teach plant transformed with a vector comprising gene from Trichoplusia ni larvea.

Wang et al teach cloning, and sequencing of cDNA for IIM from Trichopulsia ni, wherein a cDNA library was constructed from T.ni (larval) midgut mRNA; and confirmed the transcriptional and translation start sites (see, e.g, whole document) of the cloned sequences.

It would have been obvious to one of ordinary skill in the art to utilize the method of producing transformed plant taught by Kramer et al and to modify that method by incorporating the cDNA for IIM from T.ni taught by Wang et al to produce transgenic plants capable of expressing IIM protein, given the teaching by Wang et al of the importance of insect peritrophic membrane and its constituent .

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (703)306-5822 . The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith , can be reached on (703)308-3909 . The fax phone number for the organization where this application or proceeding is assigned is (703)305-7401 .

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196 .

August 27, 1999
mai


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600